Dated: March 6, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–5890 Filed 3–11–96; 8:45 am]

BILLING CODE 4140–01–M

Division of Research Grants; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meeting:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Clinical Sciences.

Date: March 8, 1996.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 4108, Telephone Conference.

Contact Person: Dr. Jules Selden, Scientific Review Administrator, 6701 Rockledge Drive, Room 4108, Bethesda, Maryland 20892, (301) 435–1785.

This notice is being published less than 15 days prior to the above meeting due to the partial shutdown of the Federal Government and the urgent need to meet timing limitations imposed by the grant review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93,893, National Institutes of Health, HHS)

Dated: March 6, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–5758 Filed 3–11–96; 8:45 am]

BILLING CODE 4140–01–M

Recombinant Research: Actions Under the Guidelines

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of Actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496, 59 FR 40170, 60 FR 20726, 61 FR 1482).

SUMMARY: This notice sets forth an action to be taken by the Director, National Institutes of Health (NIH), under the NIH Guidelines for Research Involving Recombinant DNA Molecules.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities (ORDA), Office of Science Policy, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, (301) 496–9838.

SUPPLEMENTARY INFORMATION: Today's action is being promulgated under the NIH Guidelines for Research Involving Recombinant DNA Molecules. This proposed action was published for comment in the Federal Register of November 15, 1995 (60 FR 57528), and reviewed and recommended for approval by the NIH Recombinant DNA Advisory Committee (RAC) at its meeting on December 4–5, 1995.

I. Background Information and Decisions on Actions Under the NIH Guidelines

A. Amendments to Section IV and Appendix M of the NIH Guidelines Regarding Semiannual/Annual Data Reporting

In a letter dated June 16, 1995, Dr. Gary Nabel outlined the redundant and onerous reporting requirements of multiple Federal agencies and local institutions. At a minimum, amending the NIH Guidelines to accommodate annual data reporting requirements rather than semiannual reporting requirements should greatly reduce the burden currently placed on principal investigator of human gene transfer protocols.

In a letter dated August 16, 1995, Ms. Debra Knorr, NIH Office of Recombinant DNA Activities, submitted to the Recombinant DNA Advisory Committee the intent to submit proposed amendments to the NIH Guidelines regarding annual data reporting. During the September 12, 1995, Recombinant DNA Advisory Committee meeting, Dr. LeRoy Walters, Chair, invited members of the Recombinant DNA Advisory Committee and the public to provide comments on the proposed amendments. No comments on the proposed amendments were submitted to the Office of Recombinant DNA Activities.

During the December 4–5, 1995, meeting, the Recombinant DNA Advisory Committee approved the amendments to the NIH Guidelines for annual data reporting using the current semiannual data reporting forms. The motion passed by a vote of 14 in favor, 0 opposed, and no abstentions.

The actions are detailed in Section II—Summary of Actions. I accept these recommendations, and the NIH Guidelines will be amended accordingly.

II. Summary of Actions

A. Amendments to Section IV–B–4–e, Responsibilities of the Principal Investigator During the Conduct of the Research

Section IV–B–4–e–(5) is amended to read:

''Section IV–B–4–e–(5). Comply with annual data reporting and adverse event reporting requirements for NIH-and FDA-approved human gene transfer experiments (see Appendix M–VIII, Reporting Requirements—Human Gene Transfer Protocols).''

B. Amendments to Section IV–C–3, Responsibilities of the Office of Recombinant DNA Activities

Section IV–C–3–c is amended to read:

''Section IV–C–3–c. Administering the annual data reporting requirements (and subsequent review) for human gene transfer experiments, including experiments that are reviewed solely by the FDA (see Appendix M–VI, Categories of Human Gene Transfer Experiments that May Be Exempt from RAC Review).''

C. Amendments to Appendix M–VII, Categories of Human Gene Transfer Experiments That May Be Exempt for RAC Review

Appendix M–VII is amended to read:

''Appendix M–VII. Categories of Human Gene Transfer Experiments that May Be Exempt from RAC Review.

''A proposed submitted under one of the following categories may be considered exempt from RAC review unless otherwise determined by NIH/ORDA and the FDA on a case-by-case basis (see Appendix M–VI–A, Categories of Human Gene Transfer Experiments that Require RAC Review).

Note: For proposals that are exempt from RAC review, the documentation described in Appendices M–I through M–V will be maintained by NIH/ORDA for compliance with annual data reporting and adverse event reporting requirements (see Appendix M–VIII, Reporting Requirements—Human Gene Transfer Protocols). Any subsequent modifications to proposals that were not reviewed by the RAC must be submitted to NIH/ORDA in order to facilitate data reporting requirements.

D. Amendments to Appendix M–VIII, Reporting Requirements—Human Gene Transfer Protocols

Appendix M–VIII–A is amended to read:

''*Appendix M–VIII–A Annual* Data Reporting

''Investigators who have received approval from the FDA to initiate a human gene transfer protocol (whether or not it has been reviewed by the RAC) shall be required to comply with the annual data reporting